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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,448	05/03/2001	Ismat Ullah	TN1A CIP	3068

7590 01/11/2005

Bristol -Myers Squibb Company
Patent Department
P.O. Box 5100
Wallingford, CT 06492-7660

EXAMINER

TRAN, SUSAN T

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/848,448	Applicant(s) ULLAH ET AL.	
	Examiner Susan T. Tran	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5,8-24 and 27-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5,8-24 and 27-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>03/29/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicant's Request for Continued Examination, and Amendment filed 01/14/04, and Information Disclosure Statement filed 03/29/04.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/14/04 has been entered.

Claim Objections

Claim 10 is objected to because of the following informalities:

The word "methacrylicacid" should read "methacrylic acid". Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5, 8-24 and 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hodges et al. (US 5,225,202), in view of Tanaka et al. US 5,109,003.

Hodges teaches coated pellets composition comprising drug-containing core, and an enteric coating layer surrounding the core, wherein the enteric coating will provide protection of the medicament at pH less than 3, but will allow for drug release at a pH of 4.5 or higher (see abstract; column 2, lines 35-53; and column 3, lines 10-15). Drug in the core is an acid labile drug includes dideoxyinosine (ddI) (column 3, lines 16-19). The core further comprising one or more disintegrants such as sodium starch glycolate, corn starch, or cross-linked polyvinylpyrrolidone in an amount of from about 2 to about 15%; and binder in an amount of from 0 to about 20% (column 3, lines 20-26, 54-64). The enteric coating layer comprising hydroxypropylmethylcellulose phthalate (HPMCP); plasticizer such as diethyl phthalate, triethyl citrate, or polyethylene glycol; and anti-adherent such as talc, magnesium stearate, or fumed silica (column 4, lines 17-51). The coated pellets may be filled into hard shell capsule (column 6, lines 3-4). Hodges teaches the subcoat layer between the core and outer enteric coating layer. However, Hodges discloses that the subcoat layer *may* be needed only where the core

Art Unit: 1615

includes a drug which is incompatible with the enteric coating layer (column 4, lines 59-65). It is noted that all of Hodges' examples that include the subcoat layer show the use of pravastatin as the active agent. None of the examples show subcoat layer used in ddl composition.

Hodges does not explicitly teach the amounts of the ingredients, as well as sodium carboxymethylcellulose as a binder, and methacrylic acid being the enteric coating polymer. However, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Regarding sodium carboxymethylcellulose, and methacrylic acid copolymers, it is the position of the examiner that sodium carboxymethylcellulose is a well known binder, and methacrylic acid copolymer is a well known enteric coating copolymer. However, to be more specific, Tanaka is cited, wherein Tanaka teaches an enteric coating composition comprising binder such as sodium carboxymethylcellulose, and enteric coating polymer includes HPMCP or methacrylic acid copolymers (column 5, lines 46-64). Thus, it would have been obvious for one of ordinary skill in the art to modify the coated pellets composition of Hodges using sodium carboxymethylcellulose as the binder, and methacrylic acid copolymers as the enteric coating polymer in view of the teaching of Tanaka, because Tanaka teaches an enteric coating composition comprising a well known binder and a well known enteric coating polymer such as

Art Unit: 1615

HPMCP and methacrylic acid copolymers, and because Hodges teaches an enteric coated pellets composition that has good resistance to deterioration at pH less than 3 but have good drug release properties at greater than 3.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Depui et al. is cited as of interest for the teaching of enteric coated composition for acid labile active agent, such as proton pump inhibitor.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

Art Unit: 1615

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'S. Tran', with a long horizontal flourish extending to the right.

S. Tran
Patent Examiner
AU 1615